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## Sample Clinical Quality Management Chart Review Tool

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. You may modify this as appropriate.)

Participant Identification #	Reviewed from (Visit #)Through (Visit #)
Name of Reviewer	Date of Review

				1
Indicator	Criteria	YES	NO	N/A
1. Consent	Current, IRB/EC approved version of consent signed?			
	Participant signed and dated (in ink) consent, prior to			
	study-specific procedures?			
2. Participant	Education provided per protocol?			
Education				
3. Test of	Provided per protocol and documented.			
Understanding	(If applicable)			
4. Eligibility	All eligibility criteria met and documented?			
		•	•	
5. HIV Prevention	Counseling provided per protocol, and documented?			
Counseling		1		
		•	•	
6. Lab Tests and	All required tests/ procedures performed and			
Procedures	documented?			
	Any missed tests documented, with reason provided?			
7. Concomitant Meds	Source documentation and CRF consistent?			
7. Concomitant Nicus				
	Is participant taking any prohibited meds?			
			•	
8. Study Product	Study product administered per protocol and			
Administration	documented? (If applicable)			
	Reactogenicity recorded at appropriate timeframes with			
	appropriate follow-up? (If applicable)			
9. AE/SAE/EAE Reporting	Adverse events recorded and reported properly?			
	Are there any missed (unreported ) AEs?			
	Are there any missed (unreported) SAEs?			
	Are there any missed (unreported) EAEs?			
10. Endpoints	Has the participant reached any protocol-defined endpoints?			

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	followed?			
Indicator	Criteria	YES	NO	N/A
11. Missed Visits	Has the participant missed any visits?			
	If yes, are they documented?			
12. Signatures, initials, dates	Are all entries signed and dated?			
	Are all error corrections properly executed?			

Note: Source documentation to be compared to CRF and protocol for agreement

Signature of Reviewer:	Date:	
Correction of error/problem noted in this review:		

Findings	Visit #/Date	Corrected by/date
	#/Date	
	11) Bate	
	4	
	1	•